

## *REMARKS*

### **Amendments**

The specification has been amended such that the referenced trademarks are capitalized and accompanied by their respective generic terminology as suggested by the Examiner. More specifically, the specification has been amended, where necessary, to capitalize identified trademarks, and provide definitions or generic terminology for the listed trademarks. In addition, the terms "Celite® C65" and "CELITE® C65" in the specification have been replaced with the correct trademark of "CELPURE® C65" associated with diatomaceous earth having a permeability of 0.065 Darcy, which may be used in the present invention, and the terms "Celite® C300" and "CELITE® C300" in the specification have been replaced with the correct trademark of "CELPURE® C65" associated with diatomaceous earth having a permeability of 0.300 Darcy, which may also be used in the present invention.

Claims 1, 12-16, 24 and 27 have currently been amended, claims 10 and 25 have been cancelled, and new claims 28-31 have been added.

More specifically, Claim 1 has been amended to delete each instance of the expression "an effective amount of", and to specify that the  $\beta$  (1-3)  $\beta$  (1-4) glucan is a  $\beta$  (1-3)  $\beta$  (1-4) glucan composition consisting essentially of at least about 75%  $\beta$  (1-3)  $\beta$  (1-4) glucan having a particle size of less than 0.2  $\mu\text{m}$ , less than 10% ash impurities, less than 10% protein impurities and less than 5% lipid impurities. Support for this latter amendment is provided, for example, at page 15, lines 16-32, page 19, lines 16-18 and page 21, lines 8-11 of the description. It is clear that the use of microfiltration in the presently disclosed methods to filter out material having a particle size of greater than about 0.2  $\mu\text{m}$  would inherently produce a filtrate comprising  $\beta$  (1-3)  $\beta$  (1-4) glucan having a particle size of *less* than 0.2  $\mu\text{m}$  (i.e. the filter used in such a microfiltration step would have a cut-off of 0.2  $\mu\text{m}$ ). Claim 13 has been amended for consistency with amended claim 1.

Claim 13 has been further amended to specify that the alkaline solution has a value of pH of between 9 to 10, and that the milled cereal grain or the milled part of the cereal grain is extracted

with the alkaline solution for a period of about 15 to about 45 minutes. Support for these amendments is provided, for example, at page 16, lines 14-21 and 23-24 of the description.

Claims 13 and 27 have been amended to specify that the alcohol is added in an amount of between 10% to 20% (vol/vol). Support for this amendment is provided, for example, by original claims 14 and 15, page 19, lines 30-31 of the description, and by Example 1.

Claims 14-16 have been amended to remove redundancy in view of the amendments made to claim 13.

Claim 24 has been amended to specify that the pH of the alkaline solution is from about 9.25 to about 9.75. Support for this amendment is provided at page 16, line 15 of the description.

New claims 28 and 30 are based on page 15, lines 16-32, page 19, lines 16-18 and page 21, lines 8-11 of the description.

New claims 29 and 31 are derived from claim 11.

It is submitted that these amendments do not constitute new matter, and their entry is requested.

### **Objection to Specification**

The Examiner objected to the form of the trademarks use in the specification. The amendment of the specification obviates this objection. Withdrawal of the objection is requested.

### **Objection to Claims**

The Examiner objected to claim 10 for a typographical error. The cancellation of claim 10 obviates this objection. Withdrawal of the objection is requested.

**Rejection Under 35 U.S.C. § 112, second paragraph**

The Examiner rejected claims 1-3 and 8-27 under 35 U.S.C. § 112, second paragraph for being indefinite in view of the expression “an effective amount.” Applicants submit that the amendment of claim 1 to remove this expression obviates this rejection. Withdrawal of this rejection is requested.

**Rejection Under 35 U.S.C. § 102(b)**

The Examiner rejected claims 1-3 and 8-27 under 35 U.S.C. § 102(b) as being anticipated by Westerlund et al. (*Carbohydrate Polymers* **20**:115-123, 1993). Applicants submit that the amendment of the claims obviates this rejection.

More specifically, Applicants have amended claim 1 to clarify that the  $\beta$  (1-3)  $\beta$  (1-4) glucan contained in the claimed pharmaceutical composition is a  $\beta$  (1-3)  $\beta$  (1-4) glucan composition consisting essentially of at least about 75%  $\beta$  (1-3)  $\beta$  (1-4) glucan having a particle size of less than 0.2  $\mu\text{m}$ , less than 10% ash impurities, less than 10% protein impurities and less than 5% lipid impurities.

Westerlund et al. does not teach or suggest a method for isolating the  $\beta$  (1-3)  $\beta$  (1-4) glucan composition defined in presently amended claim 1 and new claims 28-31. Westerlund et al. discloses a method that involves dialysis of a beta glucan containing fraction using a dialysis tubing having a 12 kDa molecular weight cut-off to produce a purified liquid extract containing mixed-linked beta-glucans (see page 116, right column, lines 47-53). This purification step would not, however, result in the isolation of a  $\beta$  (1-3)  $\beta$  (1-4) glucan-containing fraction consisting essentially of at least about 75%  $\beta$  (1-3)  $\beta$  (1-4) glucan having a particle size of less than 0.2  $\mu\text{m}$ , less than 10% ash impurities, less than 10% protein impurities and less than 5% lipid impurities, but rather compositions that comprise  $\beta$  (1-3)  $\beta$  (1-4) glucans having a **broader** range of particle sizes. Thus, Applicants submit that Westerlund et al. does not anticipate the claimed subject matter.

In view of the above amendments and remarks, Applicants submit that the claimed subject matter is not anticipated by Westerlund et al. Withdrawal of this rejection is requested.

### **Rejection Under 35 U.S.C. § 102(b)**

The Examiner rejected claims 1-3, 8-10 and 12-27 under 35 U.S.C. § 102(b) as being anticipated by Bhatti (US 5,518,710). Applicants submit that the amendment of the claims obviates this rejection.

More specifically, Applicants have amended claim 1 to clarify that the  $\beta$  (1-3)  $\beta$  (1-4) glucan contained in the claimed pharmaceutical composition is a  $\beta$  (1-3)  $\beta$  (1-4) glucan composition consisting essentially of at least about 75%  $\beta$  (1-3)  $\beta$  (1-4) glucan having a particle size of less than 0.2  $\mu\text{m}$ , less than 10% ash impurities, less than 10% protein impurities and less than 5% lipid impurities.

Bhatti does not teach or suggest a method for isolating the  $\beta$  (1-3)  $\beta$  (1-4) glucan composition defined in presently amended claim 1 and new claims 28-31. Bhatti discloses a method that includes removal of degraded starches from a  $\beta$  glucan extract using centrifugation, dialysis or filtration (column 3, lines 63-65). This purification step would not, however, result in the isolation of a  $\beta$  (1-3)  $\beta$  (1-4) glucan-containing fraction consisting essentially of at least about 75%  $\beta$  (1-3)  $\beta$  (1-4) glucan having a particle size of less than 0.2  $\mu\text{m}$ , less than 10% ash impurities, less than 10% protein impurities and less than 5% lipid impurities, but rather compositions that comprise  $\beta$  (1-3)  $\beta$  (1-4) glucans having a **broader** range of particle sizes. Thus, Applicants submit that Bhatti does not anticipate the claimed subject matter.

In view of the above amendments and remarks, Applicants submit that the claimed subject matter is not anticipated by Bhatti. Withdrawal of this rejection is requested.

### **Conclusion**

In view of the above amendments and remarks, Applicants believe that the present claims satisfy the provisions of the patent statutes and are patentable over the cited prior art.

Application Serial No. 10/554,290  
Amendment dated 3 March 2008  
Reply to Office Action mailed 3 December 2007

Reconsideration of the application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned to expedite the prosecution of the application.

Respectfully submitted,

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